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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040603

Application Number: 09/782,420
Filing Date: February 13, 2001
Appellant(s): SHANGOLD ET AL.

MAILED
JUN 11 2004
GROUP

Joseph S. Kentoffio
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 25, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The rejection of claims 18-22 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Darney et al, "Contraception-Associated Menstrual Problems : Etiology and Management, Dialogs in Contraception, Volume 5 (5), Spring 1998.

Bergink, Engelbert Wilhelm, EP 0 491 415A1, WIPO, (24 JUNE 1992)

Alapiessa et al, 92CA :16206, 1979

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 18-22 are rejected under 35 U.S.C. § 103 as being unpatentable over Bergink (415) in view of Darney et al and Alapiessa et al, of record, or newly cited.

Bergink (415) teaches the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for contraception employing triphasic dosage forms. Bergink teaches triphasic combined oral contraceptive methods, compositions and kits substantially similar to those herein claimed, as old and well known in the art (see abstract, claims, and pages 4-9). Claims 18-22 and the primary reference, differ as to:

1) administration levels of the medicaments, and

2) the employment of these medicaments in a 21 day regimen

Determining the active ingredient dosage level required to effect optimal contraceptive benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. In the instant case Darney et al teach, based on a published report (Johns Hopkins School of Public Health: IUDs-An update *Population Reports* 1995. XXII(5). Series B) oral contraceptives containing

ethinyl estradiol at levels greater than 20 micrograms provided a lower incidence of breakthrough bleeding and spotting as compared to higher levels of ethinyl estradiol (Darney et al, page 2, paragraph bridging columns 2 and 3). The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed contraceptive methods, and compositions.

Bergink teaches employment of a contraceptive regimen in a triphasic 24 day cycle. Alapiessa et al teach the employment of ethinyl estradiol at levels greater than 20 micrograms in combination with desogestrel at levels herein recited administered in a 21 day regimen. The skilled artisan would be motivated to employ this 21 day regimen by Bergink (page 2, line 4) teaching the persistent attempts by those in the field of contraception to "lower the total steroid dosage" in any contraceptive regimen.

Thus, in the instant case, numerous motivations exist to modify the Examiner cited prior art into the presented invention. Possessing these teachings, the skilled artisan would have been motivated to employ ethinyl estradiol at levels greater than 20 micrograms provided a lower incidence of breakthrough bleeding and spotting thereby rendering the presented claims obvious.

(11) Response to Argument

Appellant's rebuttal arguments with regard to the failure of the Examiner prior art to teach the claimed compounds at the claimed dosages are unconvincing. If Examiner art taught the claimed compounds with the claimed dosage regimen, the instant claims would have been anticipated, not obviated, as in the instant situation. The instant

regimen is obvious over the prior art of record, as an obvious variant of those oral contraceptive regimens old and well known to the skilled artisan

Attention is directed to Bergink (page 2, paragraph, 3), describing an old and well known tri-phasic contraceptive regimen providing an ethinyl estradiol (EE) dosage between 20 and 50 micrograms. This EE dosage is provided at a constant rate at all three phases of the tri-phase regimen. Examiner notes the instant claimed 25 microgram falls inside that EE dosage regimen taught as old and well known by Bergink. This regimen taught as old by Bergink, also teaches the employment of ascending progestin levels with each of the three dosage regimens in the tri-phase oral contraceptive therapy. This ascending progestin dosage is indistinguishable from the ascending progestin regimen herein claimed. Examiner notes the Bergink invention employs 20 micrograms in phases 2 and three, yet motivation to employ a higher estrogen level is provided by the Examiner cited prior art. As stated above, in the instant case Darney et al teach, based on a published report (Johns Hopkins School of Public Health: IUDs- An update *Population Reports* 1995. XXII (5). Series B) oral contraceptives containing ethinyl estradiol (EE) at levels greater than 20 micrograms as providing a lower incidence of breakthrough bleeding, and spotting, as compared to higher levels of ethinyl estradiol (Darney et al, page 2, paragraph bridging columns 2 and 3). The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed contraceptive methods, and compositions. Additionally, Bergink (page 2, paragraph 3) teach as old and well known, employing a

constant EE dosage between 20 and 50 micrograms in a tri-phase contraceptive regimen. This teaching would have motivated the skilled artisan to employ the instant claimed 25 microgram EE tri-phase contraceptive regimen and enjoyed a reasonable expectation of success, absent information to the contrary.

Appellant's arguments with regard to a 24 day cycle are unconvincing. Bergink teaches three seven day cycles with total regimen of 24 days, yet this regimen is indistinguishable from that claimed by Appellant. Attention is directed to Bergink (page 3, lines 9-30) teaching three phases including time periods between 7 and 9 days. The Bergink disclosure supports a tri-phase administration of mediciment for periods of 8 days, 9 days and 7 days. Attention is directed to instant claim 18, reciting administration time periods of between 5 to 11 days. Examiner notes the instant claim 18 encompasses a tri-phase contraception regimen of mediciment administration for periods of 8 days, 9 days and 7 days; with this regimen indistinguishable from that regimen encompassed by Bergink, as set forth above. Examiner acknowledges claim 19 reads on a 21 day, tri-phase administration. As set forth above, Bergink (page 2, paragraph, 3), describes as old and well known to theskileed artisan, a tri-phase contraceptive regimen providing an ethinyl estradiol (EE) dosage administered in a tri-phase regimen of three 7 day dosage periods. This EE dosage is provided at a constant rate at all three phases of the tri-phase regimen. This tri-phase regimen of three dosage levels, each of seven days duration, is taught a old by Bergink; this disclosure also teaches the employment of ascending progestin levels with each of the three dosage regimens in this tri-phase oral contraceptive therapy. Ascending

progestin dosage, and the tri-phase dosage in 7 day increments, set forth in the Examiner cited prior art, are indistinguishable from the tri-phase three 7 day dosages ascending progestin regimen herein claimed.

Examiner notes the compound recited by Alapiessa as ORG 2969 is desogestrel, that compound herein claimed by Appellant. Ethinyl estradiol (EE) levels and desogestrel levels herein claimed are encompassed by the Alapiessa et al contraceptive use teachings. Simply stated, the use of estrogen and progestin in various dosages and administration timings is old and well known to the skilled Artisan. Those compounds herein claimed are old and well known for use in contraceptive regimens. Tri-phase administration schema administering three different seven day dosage levels containing ascending progestin levels are well known in the art, and taught by Examiner cited prior art (see Bergink page 2, paragraph 3). Those compounds herein claimed, the dosage levels herein claimed and the administration timing herein claimed are well within those administration regimens recognized as useful for providing contraception; albeit not concomitantly. The instant claims are not anticipated: they are obvious to those of ordinary skill in the art. To modify dosage levels, or administration timing, of compounds old and well known for the same therapeutic goal would be obvious to those of normal skill in the art.

Appellant's rebuttal arguments averring unexpected benefits residing in the claimed compositions, and methods, are simply not convincing. Examiner notes the obvious nature of the instant claims. To rebut the obvious nature of the instant claims, Appellant has the burden to provide convincing evidence illustrating unexpected

benefits residing in the claimed subject matter. Appellant's burden has not been met. Attention is directed to specification pages 19-21 setting forth a study comparing 25 and 35 microgram dosages of ethinyl estradiol (EE): two problems preclude the use of this data to support patentability. First, that data presented fails to include any evidence the two contraceptive regimens produced a different result. Absent some statistical analysis illustrating a difference between the two sets of results, the skilled artisan would not be able to distinguish the effects of the higher dose from those effects set forth for the lower dose. Second, those compounds tested, and those compounds claimed are not the same. Examiner notes Appellant tested ethinyl estradiol (EE) and norgestimate, not the ethinyl estradiol (EE) desogestrel contraceptive combination herein claimed. Appellant's attempts to illustrate unexpected benefits in a claimed composition, by presenting statistically undifferentiated data flowing from a comparison of an unclaimed composition are not convincing.

. That data argued as providing an illustration of unexpected benefits fails to set forth superior contraceptive benefits residing in the claimed compositions of matter. Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

Applicants aver unexpected benefits residing in the claimed subject matter, yet fail to fails to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and

be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Appellant is neither clear and convincing, nor reasonably commensurate in scope with the instant claims. Absent claims commensurate with a clear and convincing showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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June 3, 2004

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